UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

ELI LILLY AND COMPANY, Plaintiff, v. MANGOCEUTICALS, INC. D/B/A MANGORX, Defendant.	CASE NO. 3:24-CV-02634 **JURY TRIAL DEMANDED**

PLAINTIFF ELI LILLY AND COMPANY'S AMENDED COMPLAINT
FOR FALSE ADVERTISING AND PROMOTION

Plaintiff Eli Lilly and Company ("Lilly") files this Amended Complaint for false advertising and promotion by Defendant Mangoceuticals, Inc. d/b/a MangoRx ("MangoRx"). Lilly states and alleges the following:

INTRODUCTION

1. On October 3, 2024, MangoRx announced to the public that it was launching a new weight loss drug called "TRIM," promising consumers that TRIM's "innovative formula" offers the "power of tirzepatide" in an oral dissolvable tablet form. Tirzepatide is the active ingredient found in Lilly's MOUNJARO® and ZEPBOUND®, which are FDA-approved injectable medicines, and are not available as oral tablets. In reality, MangoRx's TRIM is an unstudied and unapproved drug being falsely promoted as a safe, effective, and clinically studied medicine for patients with type 2 diabetes or obesity. Lilly is unaware of any clinical trial involving *any* oral dissolvable tirzepatide tablet, much less MangoRx's oral dissolvable tablet formulation, or any support for MangoRx's claims that TRIM is proven safe and effective. In fact, the studies that MangoRx cites to support TRIM's safety and efficacy are Lilly's studies on injectable tirzepatide, not tirzepatide of unknown origin administered via an oral dissolvable tablet. Lilly's trials did not study oral dissolvable tirzepatide tablets—let alone MangoRx's formulation—and cannot support any representations to consumers regarding the safety or efficacy of MangoRx's TRIM product. Lilly therefore brings this action to protect the public from MangoRx's dangerous, deceptive, and unlawful practices.

2. For nearly 150 years, Lilly has developed and delivered trusted and innovative medicines that save and improve patients' lives. Lilly's proprietary MOUNJARO® and ZEPBOUND® are two such first-of-their-kind medicines indicated for serious conditions afflicting millions of Americans. Approximately one in ten Americans have type 2 diabetes, and four in ten Americans are obese. To advance the treatment of these chronic conditions, Lilly used its

extensive experience and years of research to develop a new class of medicines that target patients' GLP-1 (glucagon-like peptide-1) and GIP (glucose-dependent insulinotropic polypeptide) receptors. These medicines activate both receptors to improve blood sugar control and reduce appetite and food intake.[1] FDA has approved these medicines for specific, indicated conditions and populations: MOUNJARO® for adults with type 2 diabetes, and ZEPBOUND® for adults with obesity (BMI of 30 kg/m2 or greater) or those who are overweight (BMI ≥ 27 kg/m2 or greater) and also have at least one additional weight-related condition, such as hypertension (high blood pressure), dyslipidemia (high cholesterol or fats in blood), type 2 diabetes mellitus, obstructive sleep apnea, or cardiovascular disease.

3. Both MOUNJARO® and ZEPBOUND® contain the active pharmaceutical ingredient tirzepatide. MOUNJARO® and ZEPBOUND® are the *only* FDA-approved medications that contain tirzepatide. MOUNJARO® and ZEPBOUND® are administered exclusively by subcutaneous injection. Before obtaining FDA approval for MOUNJARO® and ZEPBOUND®, Lilly undertook years of randomized controlled clinical trials evaluating the safety and efficacy of tirzepatide administered by subcutaneous injection on thousands of patients. FDA has neither evaluated nor approved *any* oral dissolvable tablet medication containing tirzepatide, and Lilly is not aware of any clinical study demonstrating that an oral dissolvable tirzepatide tablet is safe and effective.

4. MangoRx is a telehealth provider that sells drugs produced by a third-party pharmacy. Unlike MOUNJARO® and ZEPBOUND®, MangoRx's products are not approved, nor

[1] https://web.archive.org/web/20221028212253/https://www.fda.gov/news-events/press-announcements/fda-approves-novel-dual-targeted-treatment-type-2-diabetes (archived FDA MOUNJARO® approval press announcement); https://www.fda.gov/news-events/press-announcements/fda-approves-new-medication-chronic-weight-management (FDA ZEPBOUND® approval press announcement).

even reviewed, by FDA. MangoRx and its supplier are not required to follow FDA's "good manufacturing practices," nor to comply with the same controls on sterility and safe storage as manufacturers of FDA-approved medicines. Although MangoRx prescribes, sells, and distributes drugs, it is not required to report adverse events associated with those drugs—an important regulatory requirement imposed on manufacturers of FDA-approved medicines for patient safety.

5. Even though MangoRx's products have not been tested for safety, quality, or efficacy in clinical trials, MangoRx's advertising expressly tells consumers that its product offers the "power of tirzepatide" and is clinically proven to be safe and effective. MangoRx explicitly represents that these tablets "offer an effective and safe method for shedding excess weight," yet cites to no clinical study assessing the safety or efficacy of its oral dissolvable tablet. Instead, MangoRx deceptively cites to *Lilly's* clinical trials that evaluated only the efficacy of *injectable* tirzepatide. These studies do not establish the safety or efficacy of an oral dissolvable tablet, and MangoRx's reliance on Lilly's studies to support its efficacy claims for MangoRx's TRIM draws a false and improper equivalence with Lilly's FDA-approved medications.

6. MangoRx's false and misleading marketing of TRIM poses a direct patient-safety risk. MangoRx's promotional materials and public statements have the tendency to deceive the public as to the inherent nature of TRIM, and improperly lure individuals away from safe and effective FDA-approved medication. Further, MangoRx's advertising contains no notice of the risks associated with its products and deceives consumers as to the safety and efficacy of those products. Lilly therefore brings this false advertising action pursuant to the Lanham Act, 15 U.S.C. §§ 1051 *et seq*. and Texas common law.

THE PARTIES

7. Plaintiff Lilly is a corporation organized and existing under the laws of Indiana and has its principal place of business in Indiana.

8. Defendant MangoRx is a corporation organized under the laws of Texas, with its principal place of business located at 15110 Dallas Parkway, Suite 600, Dallas, TX 75248. Its registered agent is ZipDoctor, Inc., with a registered agent address at 7950 Legacy Drive Suite 400, Plano, TX 75024. MangoRx is a publicly traded company listed on the NASDAQ Stock Market under the symbol "MGRX." MangoRx completed its IPO on March 21, 2023.

JURISDICTION AND VENUE

9. The Court has subject matter jurisdiction over the Lanham Act cause of action pleaded in this case pursuant to 15 U.S.C. § 1121 and 28 U.S.C. §§ 1331 and 1338(a). The Court has supplemental jurisdiction over the common law cause of action pleaded herein pursuant to 28 U.S.C. §§ 1338(b) and 1367(a).

10. MangoRx is subject to personal jurisdiction in this District because MangoRx is incorporated in this State and operates and conducts business in this District, including unlawfully promoting oral dissolvable tirzepatide tablets. Additionally, MangoRx's principal place of business is in this District.

11. Venue is proper in this District and division pursuant to 28 U.S.C. § 1391 because MangoRx operates and conducts business in this District and division.

FACTUAL ALLEGATIONS

I. Lilly's FDA-Approved Tirzepatide Injectable Medicines

A. Lilly's Long History of Developing and Manufacturing Safe and Effective Medicines

12. Lilly is an international medicine company and pharmaceutical manufacturer. Throughout its nearly 150-year existence, Lilly has pioneered countless life-changing discoveries. Today, Lilly's medicines help tens of millions of patients across the globe, including in Texas.

13. Lilly manufactures its medicines under strict controls in state-of-the-art facilities, which employ thousands of highly specialized personnel to ensure that Lilly's medicines meet its—and global regulators'—rigorous quality and safety standards. Manufacturing active pharmaceutical ingredients, or API, and then transforming that API into medicine is a complex, methodical, and science-based process. Lilly follows Current Good Manufacturing Practices ("CGMP") across the design, monitoring, and control of manufacturing processes and facilities—from establishing robust quality management systems to obtaining quality raw materials and detecting and investigating product quality deviations. Each step—from chemical synthesis of the API to formulation, device assembly, and packaging—requires extensive testing and controls and specialized equipment.

14. Lilly is also subject to—and encourages—FDA oversight and compliance obligations, including routine regulatory inspections, adverse event reporting obligations, and post-market surveillance and studies. The same is true for other global regulators across the world. Additionally, Lilly's medicines must be, and always are, accompanied by important and highly regulated labels, instructions, and warnings, which themselves are approved by FDA.

B. MOUNJARO and ZEPBOUND

15. Using its experience and expertise, Lilly developed MOUNJARO® and ZEPBOUND®, which were approved by FDA for sale to the public in 2022 and 2023, respectively. Today, Lilly manufactures, markets, and sells MOUNJARO® and ZEPBOUND® throughout Texas and the United States, among other geographies.

16. Both MOUNJARO® and ZEPBOUND® contain tirzepatide as their API, which targets both GIP and GLP-1 hormone receptors.

17. Specifically, MOUNJARO® is designed to improve glycemic control in adults with type 2 diabetes mellitus (in addition to diet and exercise). As FDA has noted, "[d]espite the

availability of many medications to treat diabetes, many patients do not achieve the recommended blood sugar goals."[2] MOUNJARO® targets this problem. When used as directed, MOUNJARO® has been clinically proven to improve blood sugar control more effectively than other diabetes therapies.

18. ZEPBOUND® is designed to help the millions of American adults with obesity or who are overweight and have weight-related medical problems. As FDA has noted, ZEPBOUND® "addresses an unmet medical need" by targeting "chronic weight management (weight reduction and maintenance)" through a new method of hormone receptor activation.[3] Accordingly, FDA has indicated ZEPBOUND® for adults with obesity (BMI of 30 kg/m2 or greater) or those who are overweight (BMI ≥ 27 kg/m2 or greater) and also have at least one additional weight-related condition, such as hypertension (high blood pressure), dyslipidemia (high cholesterol or fats in blood), type 2 diabetes mellitus, obstructive sleep apnea, or cardiovascular disease.

19. Lilly exclusively owns the intellectual property rights related to MOUNJARO® and ZEPBOUND® and is the only lawful supplier of those medicines.

C. The FDA Approval Process

20. FDA approved MOUNJARO® and ZEPBOUND® pursuant to Lilly's marketing application, itself the culmination of a lengthy clinical trial process designed to develop, study, and bring safe medicines to patients so that—in FDA's words—"American consumers benefit

[2] https://web.archive.org/web/20221028212253/https://www.fda.gov/news-events/press-announcements/fda-approves-novel-dual-targeted-treatment-type-2-diabetes (archived FDA MOUNJARO® approval press announcement).

[3] https://www.fda.gov/news-events/press-announcements/fda-approves-new-medication-chronic-weight-management (FDA ZEPBOUND® approval press announcement).

from having access to the safest and most advanced pharmaceutical system in the world."[4] Over the course of nearly a decade, Lilly completed thirty-seven pre-clinical studies and clinical trials for these medicines, expending significant financial resources and manpower to ensure that its medicines are safe and effective.

21. FDA has only approved—and Lilly only markets—MOUNJARO® and ZEPBOUND® in injectable form. Lilly has likewise communicated with health care practitioners that tirzepatide is not available through an oral formulation.[5]

D. Lilly's Clinical Trials

22. Before a new medicine can be brought to market, it must be clinically tested through a rigorous series of studies designed to determine whether the drug is safe and effective for people to use.[6] These clinical tests are also used to study different uses for current, approved medicines that could increase effectiveness, make the medicines easier to use, and/or decrease side-effects.[7]

23. As part of the FDA approval submission for MOUNJARO® and ZEPBOUND®, Lilly conducted four separate clinical trials to study the safety and efficacy of its tirzepatide medicines for weight loss. These trials were conducted over the course of multiple years and at great expense to Lilly, costing millions and millions of dollars.

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4 https://www.fda.gov/drugs/development-approval-process-drugs (FDA explainer of new drug development process).

5 https://medical.lilly.com/us/products/answers/is-mounjaro-tirzepatide-available-as-an-oral-formulation-199489 (Lilly statement on oral tirzepatide).

6 https://www.fda.gov/patients/drug-development-process/step-3-clinical-research#The_Investigational_New_Drug_Process (FDA explainer on clinical trial steps for new drug development).

7 https://www.fda.gov/patients/clinical-trials-what-patients-need-know/basics-about-clinical-trials (FDA explainer of basics about clinical trials).

24. Lilly's trials provided it with the necessary data to demonstrate that its MOUNJARO® and ZEPBOUND® medicines are safe and effective for people to use. Without the trials, these medicines would not be eligible for FDA approval and the substantial time, labor, and capital expended by Lilly to conduct them were therefore necessary to bring the medicines to market and promote them for public use.

II. MangoRx's False and Misleading Claims

25. MangoRx is an online telemedicine platform that boasts that it does not sell "generic medications" but rather creates "expertly crafted treatments" for its customers.[8] Despite these claims, MangoRx itself does not actually create any treatment or product. Based on public filings with the Securities and Exchange Commission ("SEC"), MangoRx's unapproved drugs (including TRIM) are manufactured by EPIQ Scripts ("EPIQ").[9]

26. EPIQ is a Texas-based online, digital, mail-order pharmacy. EPIQ is 51% owned by Jacob Cohen, Chairman and Chief Executive Officer of MangoRx, who has served as the co-Manager of EPIQ since January 2022.[10] MangoRx has signed a master services agreement with EPIQ to manufacture its TRIM oral dissolvable tirzepatide tablet.[11]

27. On October 3, 2024, MangoRx announced it had launched a new weight loss treatment, describing its "latest innovation, 'TRIM'" as a "compounded, oral dissolvable

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[8] https://mangorx.com/about-us

[9] *See,* Mangoceuticals, Inc. Form 10-K for the fiscal year ended December 31, 2023 (filed Apr. 1, 2024), https://app.quotemedia.com/data/downloadFiling?webmasterId=102691&ref=318207477&type=HTML&symbol=MGRX&cdn=e424bf1d0e9dab18bf01c5d582d6f21c&companyName=Mangoceuticals+Inc.&formType=10-K&formDescription=Annual+report+pursuant+to+Section+13+or+15%28d%29&dateFiled=2024-04-01.

[10] *Id.*

[11] *Id.*

Tirzepatide tablet."[12] MangoRx launched this product in a multi-faceted ad campaign that included a press release and online advertising.

28. As set forth in detail below, MangoRx has made and continues to make numerous false and misleading statements throughout its advertising pertaining to the inherent quality of its oral dissolvable tirzepatide tablet, including (i) express statements regarding clinical studies purporting to support its efficacy claims; (ii) statements that necessarily imply equivalency between Lilly's FDA-approved injectable medication and MangoRx's untested oral dissolvable tirzepatide tablet; and (iii) statements that disparage Lilly's medicines and encourage consumers to forgo the only FDA-approved method of tirzepatide administration. These false and disparaging statements go to the inherent nature of MangoRx's untested and unapproved oral dissolvable tirzepatide tablets and deceive consumers as to the nature and quality of MangoRx's TRIM product. This presents a significant patient safety risk, as these statements having the tendency to lure the unassuming public away from using safe, effective, FDA-approved medicines and encourage the use of untested, unapproved drugs.

29. A compilation of certain of MangoRx's false and misleading advertising are discussed below and are attached hereto as **Exhibit A**.

A. Defendant's False and Misleading "Clinical Studies" Claims

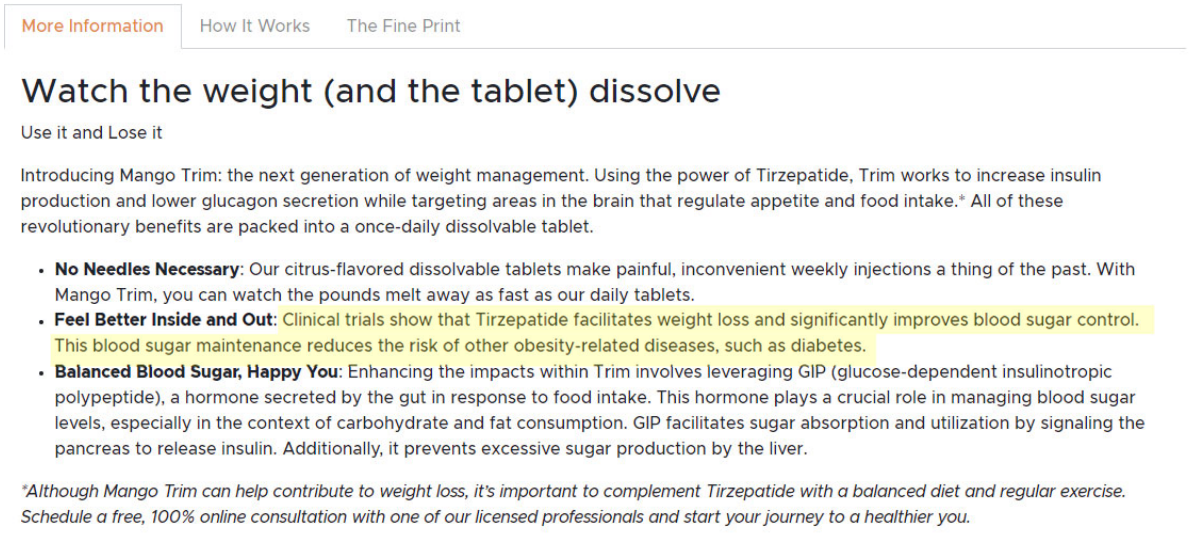
30. MangoRx's website, located at https://mangorx.com, offers TRIM (Oral Tirzepatide) Protocol for sale.[13] MangoRx's advertising campaign for its TRIM product falsely

[12] https://www.globenewswire.com/news-release/2024/10/03/2957701/0/en/MangoRx-Introduces-Oral-Tirzepatide-GLP-1-Receptor-Agonist-for-Advanced-Weight-Loss-Solutions.html.

[13] https://mangorx.com/Product/Trim.

tells consumers that TRIM, an oral dissolvable tablet, has been proven safe and effective in clinical trials when, in fact, MangoRx has not identified any such testing and Lilly is aware of none.

31. For example, on its website, MangoRx expressly references clinical trials:



32. This advertisement necessarily communicates to consumers that TRIM has been clinically tested and shown to facilitate weight loss and significantly improve blood sugar, yet there is no such clinical trial.

33. Further, in its press release and public filings,[14] MangoRx expressly promotes that tirzepatide "has gained widespread recognition for its effectiveness" and then explicitly describes the outcomes of clinical trials assessing the effectiveness of tirzepatide:

> Tirzepatide, a dual GIP and GLP-1 receptor agonist, has gained widespread recognition for its effectiveness in promoting substantial weight loss by enhancing metabolic functions and controlling appetite. Clinical trials have shown that Tirzepatide can deliver weight reductions of up to 20% in obese individuals. The phase 3 SURMOUNT-1 clinical trial showed that a significant percentage of

[14] *See,* Mangoceuticals, Inc. Form 8-K (filed Oct. 3, 2024), https://app.quotemedia.com/data/downloadFiling?webmasterId=102691&ref=318628158&type=HTML&symbol=MGRX&cdn=4f6601381c2eacdd79fe82014912381b&companyName=Mangoceuticals+Inc.&formType=8-K&formDescription=Current+report+pursuant+to+Section+13+or+15%28d%29&dateFiled=2024-10-03

> participants achieved weight loss of over 15-20% in just 72 weeks, marking it as a viable option and alternative for effective, long-term weight management.
>
> Further, in the SURMOUNT-4 trial, Tirzepatide not only helped patients achieve substantial weight loss, but it also helped patients maintain their progress over an extended period. After 88 weeks of treatment, patients experienced a total weight reduction of up to 25%, with nearly 90% maintaining at least 80% of their initial weight loss.

34. MangoRx's public filing also explicitly states that "[a]s demand for a non-invasive, ***clinically proven*** solution rises, we believe MangoRx is positioned to capitalize on this market growth."[15]

35. MangoRx also put out a "white paper"[16] that states under the heading "Clinical Efficacy and Saftey [sic]":

> Clinical trials have robustly demonstrated tirzepatide's superiority in achieving significant weight loss and enhancing glycemic control. . . . Tirzepatide has been evaluated in extensive clinical trials and has shown a favorable safety profile, with most adverse events being mild to moderate and primarily gastrointestinal in nature. The use of an ODT formulation potentially reduces gastrointestinal side effects compared to injections, thereby enhancing tolerability. Trim by MangoRx is positioned for significant impact in clinical practice, offering a safe and effective treatment alternative for metabolic diseases.

36. MangoRx's repeated references to clinical trials are clear establishment claims. An establishment claim (*i.e.*, a "tests prove" type of claim) must be supported by the kind of testing described in the advertisement. Here, because it expressly references clinical trials discussing the safety and efficacy of its TRIM product, MangoRx must have just that—clinical studies proving that its TRIM oral dissolvable tablet is safe and effective at weight loss and improving blood sugar. As discussed below, MangoRx has no such clinical studies.

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15 *Id.*

16 https://mangorx.com/wp-content/uploads/2024/10/Trim_White_Paper.pdf

37. Critically, the clinical trials that MangoRx describes (including the SURMOUNT® studies) are *Lilly's clinical studies* conducted on the *injectable* form of tirzepatide. ***None of the clinical trials that MangoRx cites assessed the efficacy of an oral dissolvable tablet***.

38. In fact, despite expressly telling consumers that its TRIM product has been proven effective in clinical trials, MangoRx does not cite a single clinical trial done on its TRIM formula or any oral dissolvable tablet. That is because, upon information and belief, MangoRx does not have any clinical data assessing the safety or effectiveness of its TRIM formula or any oral dissolvable tirzepatide tablet. Rather, MangoRx uses Lilly's clinical trial data—itself the result of years of labor and millions of dollars—without permission to seduce prospective patients away from genuine Lilly medicines and deceive patients into believing that MangoRx has performed sufficient testing to demonstrate that its TRIM formula is safe and effective.

39. MangoRx cannot rely on Lilly's clinical trials because those trials do not establish the safety and effectiveness of an oral dissolvable tablet. As explained above, FDA approvals are specific to the route of administration. MangoRx actively deceives consumers into the false impression that its oral dissolvable tirzepatide tablet is clinically proven to be safe and effective, creating serious patient safety risks.

40. MangoRx's oral dissolvable tablets have not undergone any clinical trial process, and it is a misrepresentation and puts the public at risk to suggest that Lilly's establishment of the safety and efficacy of its *injectable* MOUNJARO® and ZEPBOUND® medicines say anything about MangoRx's untested *oral dissolvable tablets* simply because they (purportedly) contain the same active pharmaceutical ingredient.

B. MangoRx's False and Misleading Efficacy Claims

41. In addition to falsely representing that its TRIM product has been clinically tested, MangoRx also falsely promotes that its TRIM is a "groundbreaking weight loss solution" and an

"innovative formula" that uses the "power of Tirzepatide" to offer an "effective and safe method for shedding excess weight . . . faster than ever before":

Trim (Oral Tirzepatide) Protocol

$399.00

Trim by MangoRx is a groundbreaking weight loss solution. Our innovative formula, using the power of Tirzepatide, offers an effective and safe method for shedding excess weight and reaching your body goals faster than ever before.

Select Pack Quantity

30 Day Supply

Order Now

42. Indeed, MangoRx expressly tells consumers that its untested and unapproved TRIM product itself is safe and effective:

More Information | How It Works | The Fine Print

The Weigh Trim Works

Each component of Mango Trim's revolutionary formula is chosen to create a safe and effective approach to weight management.

- Tirzepatide: Tirzepatide works by regulating appetite and food intake. It magnifies the effects of the glucagon-like peptide-1 (GLP-1) and glucose-dependant insulinotropic polypeptide (GIP) receptors, allowing them to extend their activity for days. This allows the body to better regulate appetite and food intake, leading to weight loss and glycemic control. To sum it up: take Trim, feel less hungry, and lose weight more easily.
- Citrus-Flavored Orally Dissolvable Tablet (ODT): Our once-daily dissolvable tablets allow for discreet, on-the-go consumption. No weekly shots, no needles, just a citrus-flavored tablet between you and your dream body.

Ready to take the next step? Schedule a free, 100% online consultation with one of our licensed professionals to learn if Mango Trim is right for you.

43. Similarly, in an October 3, 2024, press release, MangoRx's CEO, Jacob Cohen, stated that MangoRx's oral dissolvable tirzepatide tablet "enhances patient convenience without

sacrificing efficacy" and its "telemedicine platform ensures that patients have access to safe, reliable options."[17]

44. MangoRx deceives consumers into believing that regulatory and scientific bodies, including FDA, have deemed tirzepatide consumed via oral dissolvable tablet to be safe and effective. Quite the contrary: there is no such proof. No regulator—let alone FDA—has evaluated the safety or effectiveness of oral dissolvable tablets or any other non-injectable routes of administration for tirzepatide. Lilly's clinical trial results are directed to specific dose formulations of injectable tirzepatide. Nothing in those studies indicates what a safe or effective dosage of *oral dissolvable tablets* of tirzepatide would be, let alone suggest that the approved doses would be effective if administered orally. Lilly is unaware of any data supporting MangoRx's representations that its oral dissolvable tirzepatide tablets are effective. Thus, Lilly's clinical studies do not and cannot establish the proposition for which they are cited by MangoRx, namely that an oral dissolvable tablet form of tirzepatide is safe and effective.

45. Although the claims regarding safety and efficacy are often made in direct proximity to MangoRx's claims regarding clinical trials, even without such an express reference to clinical trials, these aggressive health benefit claims nonetheless on their own necessarily imply that MangoRx has testing that establishes the safety and efficacy of its product. As noted above, and on information and belief, MangoRx has no such clinical testing or data to support its advertising claims.

46. As shown above, MangoRx's advertising also expressly tells consumers that TRIM itself makes users "feel less hungry, and lose weight more easily" thus likewise communicating

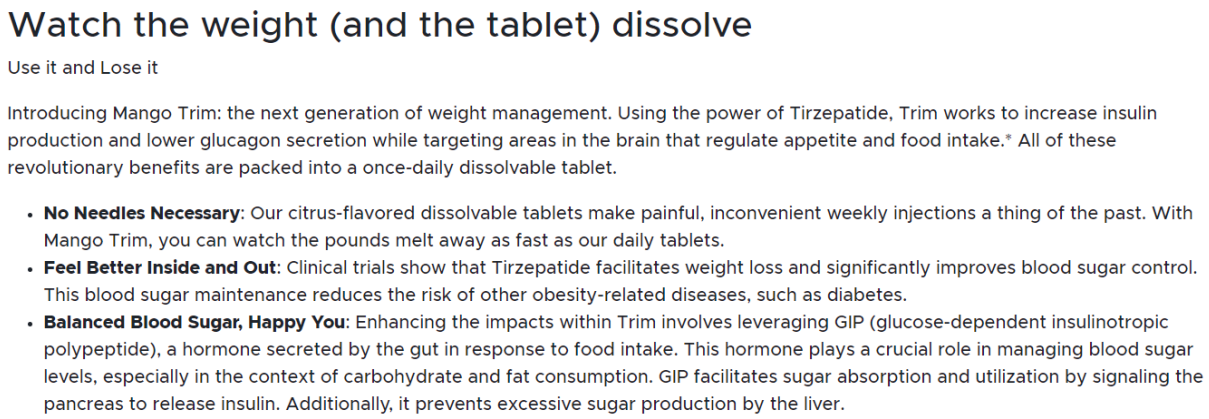
[17] https://www.globenewswire.com/news-release/2024/10/03/2957701/0/en/MangoRx-Introduces-Oral-Tirzepatide-GLP-1-Receptor-Agonist-for-Advanced-Weight-Loss-Solutions.html

that TRIM is an effective weight loss treatment. MangoRx's advertising necessarily communicates to consumers that it has tested the TRIM product, and that its particular, supposedly "groundbreaking" formula has been proven safe and effective.

C. Defendant's Disparagement of Lilly's FDA-Approved Route of Administration

47. Not content to just promote the alleged benefits of its oral dissolvable tablet, MangoRx's advertising also claims to offer a *superior* option over Lilly's MOUNJARO® and ZEPBOUND.® Specifically, MangoRx uses the results of Lilly's clinical trials without permission to falsely state that TRIM is effective for achieving the same outcomes as Lilly's medicines while also promoting TRIM as the more convenient option for "on-the-go consumption" as noted above.

48. Moreover, MangoRx disparages Lilly's FDA-approved and clinically tested method of treatment, claiming its injections are "painful" and "inconvenient":



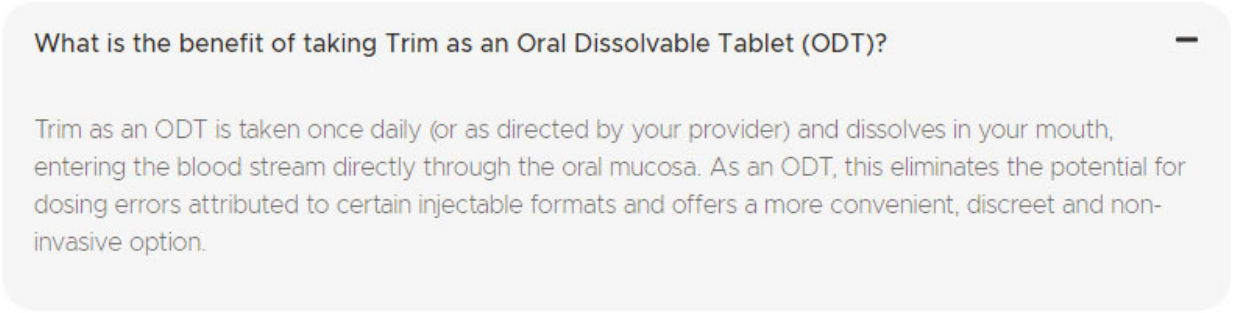
Watch the weight (and the tablet) dissolve

Use it and Lose it

Introducing Mango Trim: the next generation of weight management. Using the power of Tirzepatide, Trim works to increase insulin production and lower glucagon secretion while targeting areas in the brain that regulate appetite and food intake.* All of these revolutionary benefits are packed into a once-daily dissolvable tablet.

- **No Needles Necessary**: Our citrus-flavored dissolvable tablets make painful, inconvenient weekly injections a thing of the past. With Mango Trim, you can watch the pounds melt away as fast as our daily tablets.
- **Feel Better Inside and Out**: Clinical trials show that Tirzepatide facilitates weight loss and significantly improves blood sugar control. This blood sugar maintenance reduces the risk of other obesity-related diseases, such as diabetes.
- **Balanced Blood Sugar, Happy You**: Enhancing the impacts within Trim involves leveraging GIP (glucose-dependent insulinotropic polypeptide), a hormone secreted by the gut in response to food intake. This hormone plays a crucial role in managing blood sugar levels, especially in the context of carbohydrate and fat consumption. GIP facilitates sugar absorption and utilization by signaling the pancreas to release insulin. Additionally, it prevents excessive sugar production by the liver.

49. Likewise, on its FAQ page, MangoRx again touts the benefits of oral dissolvable tablets over Lilly's FDA-approved and clinically tested route of administration:



50. MangoRx's advertising therefore promotes TRIM as more convenient, less painful, and just as safe and effective as Lilly's FDA-approved and clinically tested medicines. But as discussed above, the only FDA-approved and clinically tested route of administration for tirzepatide is via subcutaneous injection. MangoRx's advertisements are designed to mislead consumers into selecting its untested, unapproved, potentially dangerous and ineffective products as preferable over FDA-approved and clinically tested medications. This places consumers at unnecessary and impermissible risk of harm, given that MangoRx's oral dissolvable tirzepatide tablets are not FDA-approved, have not been clinically tested, and are not reviewed for safety, quality, or efficacy.

III. Harm from Defendant's Conduct

51. MangoRx's false, misleading, and reckless promotion and sale of its products has harmed Lilly and consumers, and will continue to do so if left unchecked.

52. First, MangoRx's misrepresentations lure reasonable consumers away from obtaining safe and effective treatment with MOUNJARO® and ZEPBOUND® on the false promise that MangoRx's oral dissolvable tablet that purport to contain tirzepatide is effective in helping people treat diabetes and address chronic weight management. This not only has and will continue to result in lost sales for Lilly, but more importantly risks severe harm to consumers—at best financially but potentially far worse.

53. Second, MangoRx's misrepresentations cause irreparable damage to Lilly's brand and customer goodwill by promising results that consumers will not obtain from MangoRx's products. When consumers fail to achieve desired results from TRIM, consumers will associate tirzepatide with being ineffective in general—an outcome made even more probable given MangoRx's reliance on Lilly's clinical studies. This is particularly acute with TRIM, because the average consuming public likely does not know or appreciate the impact the difference in routes of administration on the efficacy of tirzepatide. Therefore, consumers will undoubtedly draw negative inferences as to Lilly's medications as well.

FIRST CAUSE OF ACTION
False and Misleading Advertising and Promotion
in Violation of 15 U.S.C. § 1125(A)(1)(B)

54. Lilly repeats and realleges each and every allegation above as if fully set forth herein.

55. MangoRx's commercial advertising claims described herein are false and misleading in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

56. MangoRx has knowingly and willfully made materially false and misleading statements in its commercial advertisements for its oral dissolvable tirzepatide tablets (including its website, press releases, and public filings). These statements regarding alleged clinical studies on the safety, quality, and effectiveness of MangoRx's oral dissolvable tirzepatide tablet have influenced and are likely to continue to influence consumers' purchasing decision—specifically, the decision to purchase TRIM instead of Lilly's FDA-approved medicines. As a result, MangoRx is steering patients with serious diseases like diabetes and obesity away from obtaining safe, effective, available, and FDA-approved treatments. MangoRx's unlawful conduct is putting health, safety, and lives at risk.

57. MangoRx has caused its false statements to enter interstate trade or commerce.

58. As a direct and proximate result of MangoRx's false and deceptive campaign, Lilly is suffering immediate and continuing, competitive irreparable injury for which there is no adequate remedy at law.

59. As a direct and proximate result of MangoRx's false and deceptive campaign, Lilly has suffered and will continue to suffer significant monetary damages and discernible competitive injury by the loss of goodwill.

60. This is an exceptional case under 15 U.S.C. § 1117.

61. Lilly is entitled to injunctive relief as well as monetary damages, and other remedies provided by Sections 1116, 1117, and 1118, including MangoRx's profits, treble damages, reasonable attorneys' fees, costs, and prejudgment interest.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Lilly prays that this Court enter judgment in its favor on its claim for relief set forth above and award it relief including, but not limited to, the following:

1. An Order declaring that MangoRx:

   a. Engaged in false and misleading advertising and promotion, in violation of 15 U.S.C. § 1125(a); and

   b. That the above act was willful and knowing.

2. An injunction preliminarily and then permanently enjoining and restraining MangoRx and its officers, agents, servants, employees, and attorneys and all persons acting in concert or participation with any of them, from:

   a. Falsely stating or suggesting that MangoRx's oral dissolvable tirzepatide tablets are approved by FDA, have been the subject of clinical studies, or achieve certain therapeutic outcomes;

   b. Engaging in any unfair competition with Plaintiff Lilly; and

c. Engaging in any deceptive or unfair acts.

3. An Order requiring MangoRx and its officers, agents, servants, employees, and attorneys and all persons acting in concert or participation with any of them, to engage in corrective advertising by informing consumers that:

a. MangoRx's oral dissolvable tirzepatide tablets do not contain the same formulation as MOUNJARO® or ZEPBOUND®;

b. MangoRx's oral dissolvable tirzepatide tablets do not contain the same dosage as MOUNJARO® or ZEPBOUND®;

c. MangoRx's oral dissolvable tirzepatide tablets are not and have never been approved by FDA;

d. MangoRx's oral dissolvable tirzepatide tablets have never been studied in clinical trials;

e. Lilly's clinical trials do not substantiate any claims about the safety and efficacy of MangoRx's oral dissolvable tirzepatide tablets; and

f. MangoRx's oral dissolvable tirzepatide tablets have never been demonstrated to be safe or effective.

4. An Order directing MangoRx to file with this Court and serve on Lilly's attorneys, thirty (30) days after the date of entry of any injunction, a report in writing and under oath setting forth in detail the manner and form in which it has complied with the Court's injunction.

5. An Order requiring MangoRx to account for and pay to Lilly any and all profits arising from the foregoing acts of false advertising.

6. An Order requiring MangoRx to pay Lilly compensatory damages in an amount as yet undetermined caused by the false advertising and trebling such compensatory damages for payment to Lilly in accordance with 15 U.S.C. § 1117 and other applicable laws.

7. An Order for pre-judgment and post-judgment interest on all damages.

8. An Order requiring MangoRx to pay Lilly's costs and attorney fees in this action pursuant to 15 U.S.C. § 1117, Texas state law, and any other applicable provision of law.

9. Other relief as the Court may deem appropriate.

JURY DEMAND

Lilly hereby demands a jury trial for all issues so triable.

Dated: January 30, 2025

Respectfully submitted,

/s/ James John Lomeo

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